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maine standards COMPANY

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K053247."

Submitter: Maine Standards Company
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Contact: Christine Beach, Dir. RA/QA

Summary prepared on: November 7, 2005

Device classification name: Multi-Analyte Controls, All Kinds (Assayed and Unassayed)
Device description: Quality control material (assayed and unassayed)*
Proprietary Name: VALIDATE® Cardiac Markers Calibration Verification Test Set
Regulation Number: 21 CFR 862.1660
Product Code: JJY*
***Note**: There is no FDA product code for calibration verification / linearity materials. Therefore, as with previous submissions by Maine Standards and other calibration verification / linearity manufacturers, JJY has been selected as the "best fit" FDA code for this product.*
Regulatory Class: Class I

Predicate Device:

1. Bio-Rad Liquichek Cardiac Markers Control LT (K040277), Bio-Rad Laboratories, Irvine, CA
2. DOCUMENT CK-MB CAL•VER, Microgenics Corporation, Fremont, CA
   ***Note**: While the package insert for this commercially available product states that it is intended for in vitro diagnostic use in the determination of linearity and calibration verification for CK-MB and the accompanying worksheet provides lot specific analyte values, a k number could not be identified through the CDRH database.*

Device description: VALIDATE Cardiac Markers Calibration Verification Test Sets are human based calibration verification materials containing multiple levels used to establish the relationship between theoretical operation and actual performance of the included analytes. There exists a linear relationship among each set of solutions.

Intended use: The VALIDATE Cardiac Markers Calibration Verification Test Sets are used by trained laboratory professionals for quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for the analytes listed on the package insert. These materials are not intended for use as routine quality control materials or as calibration materials.

Comparison of VALIDATE® CM 1 Calibration Verification Test Set to the predicate devices:

Table 1 compares characteristics of the VALIDATE® CM1 Calibration Verification Test Set With those of the DOCUMENT CK-MB CAL•VER and Bio-Rad Liquichek Cardiac Markers Control LT.

TABLE 1 - Comparison of Devices

	VALIDATE® CM1	DOCUMENT® CK-MB CAL•VER	Bio-Rad Liquichek™ Cardiac Markers Control LT
Catalog #	**CM1**	**M-116**	
Intended Use	For *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry analyzers.	For use in the quantitative determination of linearity, calibration verification, verification of analytical measurement range (AMR), and clinical reportable range (CRR) of manual and automated chemistry analyzers.	For use as an assayed quality control serum to monitor the precision of laboratory testing procedures
Analytes	CK-MB, MYO	CK-MB	CK-MB, MYO, Digitoxin, Homocysteine, NT-ProBNP, Troponin-I, Troponin-T
Matrix	Human Serum	Human Serum	Human Serum
Number of Levels	6 including zero	6	3
Preparation	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use
Packaging	6 x 3.0mL	6 x 5.0mL	6 x 3.0mL
Stability	Until expiration	Until expiration	10 days after opening
Storage	-10 to -20°C	-10 to -20°C	-10 to -20°C

The performance of VALIDATE® CM1 Calibration Verification Test Set solutions on the Abbott AxSym instrument system as compared to DOCUMENT® CK-MB CAL•VER and Bio-Rad Liquichek Cardiac Markers Control LT has been shown to be substantially equivalent using pre-production lots of VALIDATE® CM1 Calibration Verification Test Sets.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 13 2006

Ms. Christine Beach
Director, QA/RA
Maine Standards Co.
765 Roosevelt Trail Suite 9A
Windham, ME 04062

Re: k053247
Trade/Device Name: VALIDATE® Cardiac Marker Calibration Verification Test Sets
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: November 10, 2005
Received: November 21, 2005

Dear Ms. Beach:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 053247

Device Name: VALIDATE® Cardiac Marker Calibration Verification Test Sets

Indications For Use:

The VALIDATE® Cardiac Marker Calibration Verification Test Sets are used by trained laboratory professionals for quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for CK-MB and Myoglobin.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

R. Chelen for Carol Benson

Division Sign-Off

Office of In Vitro Diagnostic **Device** Evaluation and Safety

K053247